

AMENDMENTS IN THE CLAIMS

1. (Currently Amended) A controlled release formulation comprising:
a protein mixed with a polysaccharide stabilizer comprising microparticles;
a surfactant coated on the microparticles; and [[and encapsulated in]]
a biodegradable polymer encapsulating the surfactant coated microparticles.
2. (Cancelled)
3. (Original) The controlled release formulation according to claim 1, wherein the biodegradable polymer comprises homo or heteropolymers of lactic and glycolic acids.
4. (Original) The controlled release formulation according to claim 1, wherein the biodegradable polymer is selected from the group consisting of hydrophobic bioabsorbable polymers such as polyglycolide, polylactide (D, L, DL), polydioxanones, polyester carbonates, polyhydroxyalkonates, polycaprolactone (polylactones), polyethylene glycol, and copolymers thereof; preferably polyglycolide or polylactide, or a copolymer or polyglycolide-caprolactone of polyglycolide and polylactide, polylactide-polycaprolactone.
5. (Currently Amended) A controlled release formulation comprising:
 - a. a protein;
 - b. a stabilizer mixed with the protein; and
 - c. a surfactant coated on the stabilizer protein mixture comprising surfactant coated microparticles; and
 - d a biodegradable polymer in which the surfactant coated microparticles are encapsulated.
6. (Cancelled)

7. (Currently Amended) The controlled release formulation according to claim 5 ~~[[6]]~~, wherein the stabilizer has a charge and the surfactant has a charge opposite to the stabilizer.

8. (Original) The controlled release formulation according to claim 5, wherein the stabilizer is uncharged and the surfactant is uncharged.

9. (Original) The controlled release formulation according to claim 5, wherein the stabilizer is uncharged and the surfactant is charged.

10. (Cancelled)

11. (Currently Amended) A controlled release formulation comprising:

- a. a protein;
- b. a stabilizer mixed with the protein wherein the protein and stabilizer mixture comprises a stabilized particle; ~~[[and]]~~
- c. a surfactant coated on the particle; and
- d. a biodegradable polymer encapsulating the surfactant coated particle; and wherein the encapsulated surfactant coated particle comprises a microparticle ~~[[protein stabilizer mixture]]~~.

Claims 12 through 20 are cancelled.

21. (Currently Amended) A method for making stabilized protein particles comprising:

- a. providing a solution of protein;
- b. providing a solution of stabilizer;
- c. mixing the solutions;
- d. generating microparticles from the mixture; and
- e. coating the microparticles with surfactant;
- f. encapsulating the surfactant coated microparticles in a biodegradable polymer.

22. (Cancelled)

23. (Currently Amended) The method according to claim 21 [[22]], wherein the stabilized protein microparticles [[particles]] are suspended in an organic solvent and coated with a surfactant in an organic solvent.

24. (Currently Amended) The method according to claim 21 [[22]], wherein the organic solvent is selected from the group consisting of ethanol, dichloromethane, dimethyl sulfoxide, dimethyl formamide and mixtures thereof.

25. (Currently Amended) The method according to claim 21 [[22]], wherein the protein and stabilizer are mixed in a ratio of stabilizer:protein of about 500:1 to about 1:1.

26. (Currently Amended) The method according to claim 21 [[22]], wherein the protein and stabilizer are mixed in a ratio of stabilizer:protein of about 10,000:1 to about 50:1.

27. (Currently Amended) The method according to claim 21 [[22]], wherein when the protein comprises a therapeutic protein, the protein and stabilizer are mixed in a ratio of stabilizer:protein of about 500:200 to about 1:1.

28. (Currently Amended) The method according to claim 21 [[22]], wherein when the protein comprises a therapeutic protein, the protein and stabilizer are mixed in a ratio of stabilizer:protein of about 100,000:1 to about 1:1.

29. (New) The controlled release formulation according to claim 11, wherein the stabilizer is selected from the group consisting of polysaccharide, carrier protein, and mixtures thereof.

30. (New) The polysaccharides according to claim 29, wherein the polysaccharide is selected from the group of polysaccharide gums consisting of guar gum, gum arabic, gum karaya, gum ghatti, locust bean gum, tamarind gum, carageenan gum, and pectin or mixtures thereof.

31. (New) The controlled release formulation according to claim 11, wherein when the stabilizer is a carrier protein, the stabilizer is selected from the group consisting of HSA, gelatin, BSA, and mixtures thereof.

32. (New) The controlled release formulation according to claim 11, wherein the biodegradable polymer is selected from the group consisting of hydrophobic bioabsorbable polymers such as polyglycolide, polylactide (D, L, DL), polydioxanones, polyester carbonates, polyhydroxyalkonates, polycaprolactone (polylactones), polyethylene glycol and copolymers thereof;

33. (New) The controlled release formulation according to claim 11, wherein the biodegradable polymer is selected from a group of polymers that are sensitive to environmental conditions such as temperature or pH.

34. (New) The controlled release formulation according to claim 11, wherein the biodegradable polymer is a block copolymers of polyethylene glycol and poly (lactic-co-glycolic) acid polymers.

35. (New) The controlled release formulation according to claim 11, wherein the biodegradable polymer is a graft copolymer of polyethylene glycol and poly (lactic-co-glycolic) acid polymer.

36. (New) The controlled release formulation according to claim 11, wherein the particles of surfactant coated stabilized protein are dispersed within the encapsulant.

37. (New) A method for stabilizing a protein comprising:
- a. providing a protein in an aqueous solution;
 - b. adding an aqueous polysaccharide gum to the protein aqueous solution;
 - c. spray drying or lyophilizing the polysaccharide gum and protein solution to produce particles;
 - d. coating the polysaccharide gum and protein particles with a surfactant;
 - e. encapsulating the coated particles within a biodegradable polymer.